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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/806,915

Applicant(s)

NICOL ET AL.

Examiner

BLESSING M. FUBARA

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8-11,13-18,20-25,28-30 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8-11,13-18,20-25,28-30 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The examiner acknowledges receipt of amendment and remarks filed 8/10/09 and supplemental amendment filed 11/02/09. Claims 1, 2, 11, 24, 25 and 34 are amended. Claims 7 and 12 are canceled. Claims 1, 2, 8-11, 13-18, 20-25, 28-30 and 34 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn in view of the amendment to claims 1, 2, 11, 25 and 34.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. Claims 1, 2, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265) in view of Brever et al. (US 3,946,115).

4. Lambert discloses an antacid composition that comprises antacid, 4.0-8.0% oil, antioxidant, and 46.0-84.5% carrier (column 2, lines 1-34; column 2, lines 5-47 and claims 1-3). The antacid is selected from the group consisting of aluminum phosphate, dihydroxy-aluminum-sodium-carbonate, dicalcium phosphate, calcium carbonate and mixtures thereof (column 2, lines 1-4, 48-52). The carrier is selected from the group consisting of ground wheat, spray dried whey, steam rolled oats and mixtures thereof (column 2, lines 11-13; column 3, lines 16-18). The antacid such as calcium carbonate is a stomach antacid meeting the requirement of the claimed composition to have stomach antacid; the carrier such as ground wheat or rolled oats or mixtures thereof meets the limitation of fiber and the amount of 46-84.5% of carrier, and specifically the 60.45%, derived from 30-45% ground wheat and 20.0% rolled oats (column 2, lines 33 and 34) meet the limitation of 15-70% fiber or points within the disclosed range of 46-84.5% intersects points within the claimed range of 15-70% fiber of claims 1, 2. Points within the disclosed amount of 4-8% oil intersects points within the recited range of 5-20% oil, thus meeting the requirements of 5-20% oil of claims 1, 2. The presence of carbohydrate in oats meets the requirement of starch in claim 8 since in one of the embodiments of Lambert, the rolled oat is present about 20% such that the amount of the carbohydrate is less than 20% when about 20% is less than 20% at say 19.6 and because oats is comprised of fiber and carbohydrate. The composition of Lambert is administered to horses to reduce gastric acid (column 1, lines 52-54). Inhibiting gastric acid secretion as recited in claim 9 is what the composition will do in the stomach of horses, and in this respect the composition of Lambert would also inherently do that but as noted, Lambert specifically teaches that the antacid in composition reduces gastric acid levels (column 2, lines 53, 54).

5. Lambert does not describe the size of the wheat or rolled oats. Lambert does not state the size/length of the antacid composition. But horse feeds are generally extruded and when extruded, these feeds have certain dimensions of length. For example, Brever discloses extruded horse feed as having size and shape and in this particular instance, the length of the extrudate ranges from 1/8 inches to 3 inches (0.318 to 7.62 cm). Thus, taking the teachings of Lambert and the disclosure of Brever relied upon for teaching that horse feeds are extruded, one having ordinary skill in the art at the time the invention was made has the technical capability to use known extrusion technique and extrusion device to prepare the composition of Lambert so that the resulting extrudate would have certain dimensions as per the geometrical design of the device; In the case of the Brever reference, the size would range from 1/8 inches to 3 inches (0.318 to 7.62 cm).

6. Claims 1, 2 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265) in view of Brever et al. (US 3,946,115) and further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

7. Lambert in view of Brever is described above to render obvious claims 1, 2, 8 and 9. Lambert teaches calcium carbonate stomach antacid for reducing gastric acid. Lambert does not use the proton pump inhibitor or histamine type-2 antagonist as the stomach antacid as recited in claim 10. But one stomach antacid can be used in place of the other to achieve the same effect of gastric acid reduction. Pagan specifically teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161). Therefore, taking the teachings of Lambert and Pagan, one

having ordinary skill in the art at the time the invention was made would reasonably expect that histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161) for the carbonate antacid of Lambert would produce the expected reduction of gastric acid.

8. Claims 11, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265) in view of Brever et al. (US 3,946,115).

9. Lambert has been described above to render obvious claims 11 and 24. Lambert in view of Brever has also been described above to render obvious claim 1 whose composition is the same as the composition in claim 25 that is administered to treat or ameliorate animal stereotypy or to minimize the risk of developing animal stereotypy, and this involves or comprises minimizing or reducing ulcer formation or treating ulcers formed in the stomach. Therefore, the administration of the composition of Lambert in view of Brever would inherently treat stereotypy before it becomes fixed as discussed.

10. Lambert does not say that ulcer formation is minimized or reduced. But, in the claims, it is the administration of the antacid composition that leads to the reduction or minimization of ulcer. Brever was relied upon to show that animal feed or horse feed could have the designated length. Therefore, taking the teaching of Lambert and relying on Brever to show that horse feed extruded have sizes of from 1/8 inches to 3 inches (0.318 to 7.62 cm), one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that administration of the chopped fiber containing antacid composition to a horse would effectively reduce gastric acid, which means ameliorating or treating stereotypy and in turn means

minimizing the risk of developing animal stereotypy, and further in turn is a minimizing or reduction in ulcer formation or treatment for ulcers formed in the stomach.

Response to Arguments

11. Applicant's arguments filed 11/02/09 have been fully considered but they are not persuasive.

12. Lambert in view of Brever:

13. Applicant argues that Brever does not remedy the deficiencies of Lambert as presented in the amendment filed 8/10/09, that there is no disclosure in Brever that the fiber present in the extruded horse feed includes chopped fiber that is about 1-7 cm long, so that the combination of the cited references does not render the subject matter obvious. In the remarks filed 8/10/09, applicant argues that Lambert does not disclose that at least some of the fiber in the composition is chopped fiber, applicant disagrees that horse feeds are generally extruded and that it was normal practice before applicant's invention to mix and pellet components of horse feed and not to extrude the feed, that the process of grinding in Brever involves mixing and finely grinding proteinaceous, farinaceous, fibrous and other nutritional materials before extrusion so that the fiber may be considerably less than 1 cm long before extrusion.

14. The examiner disagrees with the applicant that Brever does not remedy the deficiencies of Lambert in view of the following: It is true that Lambert does not disclose the chopped fiber that is 1-7 cm long and that is why Brever is used to show that horse feeds can be extruded and the length of the extruded feed ranges from 1/8 inches to 3 inches (0.318 to 7.62 cm) and a length of 0.318-7.76 cm encompasses the recited length of 1-7 cm and applicant has not provided any evidence that the range of 1-7 cm provides unexpected results. Second, although applicant

states that horse feeds are not normally extruded, Brever, published 1976 before applicant's invention describes extruding horse feeds and Brever is relied upon for teaching that. Therefore, Brever remedies Lambert's failure to teach length of fibers used in horse feeds. Thirdly, there is no evidence that the fibers are less than 1 cm in length.

15. Claims 11, 13-17, 23, 24 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265).

16. Lambert is described above as administering composition comprising antacid to reduce gastric acid levels. Claims 11 and 24 treat or ameliorate animal stereotypy by controlling the stomach pH by oral administration of stomach antacid. Thus, it is the antacid that produces the effect of controlling the stomach pH that leads to the treatment or amelioration of stereotypy. Therefore, the antacid composition of Lambert would inherently treat or ameliorate animal stereotypy, in this case, stereotypy in the horse, by the oral administration of the composition comprising the antacid to reduce gastric acid levels.

17. With regards to recently weaned or weaning as recited in claim 14, weaned as recited in claim 15, being weaned as recited in claim 22, following weaning as recited in claim 23, it is the examiners position that because the horses are placed in the study in Lambert, it flows that these horses placed in the study have to have been weaned although the art is silent on that. Therefore, since these horses are placed in the study, the horses in the Lambert's study encompasses the scope of recently weaned or weaning as recited in claim 14 or being weaned as recited in claim 22 or following weaning as recited in claim 23 or weaned as recited in claim 15

or before birth. For claim 17, the antacid composition of Lambert that is orally administered intrinsically inhibits the secretion of the acid in the stomach and thus meets the claim.

18. Lambert does not state that the antacid is administered before the stereotypy is fixed as required by amended claims 11 and 24. The claimed method treats or ameliorates stereotypy in animals and the method comprises orally administering stomach antacid to the animal.

Lambert's antacid composition is administered to reduce gastric acid. Thus, because Lambert specifically administers antacid to the horse to reduce gastric acid, it would flow that the stomach pH of the horse is controlled before or shortly after the horse develops acid conditions, which in turn would mean that the stereotypic behavior treated by oral administration of antacid is present in the horse (claim 13) or before the stereotypic behavior is permanent or "fixed" as now recited in claims 11 and 24. Therefore, taking the teaching of Lambert, one having ordinary skill in the art at the time the invention was made would reasonably expect administering the antacid of Lambert to horses would reduce gastric/stomach acid and in turn treat or ameliorate stereotypy before it is fixed.

Response to Arguments

19. Applicant's arguments filed 11/02/09 have been fully considered but they are not persuasive.

20. Applicant argues that claim 11 is allowable over Lambert because Lambert does not disclose or suggest a link between stomach acidity and animal stereotypy, 'let alone the administration of a stomach antacid before stereotypy becomes fixed.' Applicant further argues that there is no connection between ulcer formation and stereotypy prior to applicant's invention, the claimed method of claims 24 and 25 and allowable over the prior art.

21. The examiner disagrees in view of the reasons that follow: a) Claim 25 is not included in the above rejection; b) the method treats stereotypy by administering composition comprising antacid. Lambert administers antacid to horses. The antacid of Lambert meets the antacid limitation of claim 11. The antacid administered in the claims provides treatment or amelioration of stereotypy. Because same compounds must have the same properties or effects, the antacid administered by Lambert must also provide treatment of stereotypy or ameliorate stereotypy. While, Lambert has not suggested a link between stomach acid and stereotypy, the compounds administered are the same and would have the same effect in the animal; c) with regard to ulcer formation and minimization of the risk of ulcer formation, it is noted here also that that the claimed method administers antacid to effect minimizing risk of ulcer formation so that Lambert's oral administration of antacid would also lead to minimization of the risk of ulcer formation.

22. Therefore, claims 11, 13-17, 23, 24, and 28-30 are not patentable over Lambert.

23. Claims 11, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265) in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

24. Lambert is described above as rendering obvious amended claim 11. Lambert teaches calcium carbonate stomach antacid for reducing gastric acid. Lambert does not use the proton pump inhibitor or histamine type-2 antagonist as the stomach antacid as recited in claim 18. But one stomach antacid can be used in place of the other to achieve the same effect of gastric acid reduction. And, Pagan specifically teaches treating equine ulcers by neutralizing acidity with

histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161). Therefore, taking the teachings of Lambert and Pagan, one having ordinary skill in the art at the time the invention was made would reasonably expect that histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161) for the carbonate antacid of Lambert would produce the expected reduction of gastric acid.

Response to Arguments

25. Applicant's arguments filed 11/02/09 have been fully considered but they are not persuasive.

26. Lambert in view of Pagan:

27. Applicant argues that there is no disclosure in Lambert or Pagan that the fiber is present in the composition as chopped fiber having a length of from 1-7 cm; neither Lambert nor Pagan teaches links between stomach acidity and stereotypy, "let alone treatment or amelioration of animal stereotypy, or minimizing the risk of an animal developing animal stereotypy, by administering a stomach antacid before the stereotypy becomes fixed.

28. The examiner disagrees. Claim 11 does not recite length of the fiber. The method of treating or ameliorating animal stereotypy, or minimizing the risk of an animal developing animal stereotypy involves the administration of stomach antacid. Similarly, Lambert administers stomach antacid and the same effect will derive from the same compound. Pagan was relied upon for using the specific antacid for reducing stomach acid.

29. With regards to claim 10 rejected in paragraph 6 of this office action. Pagan was relied upon for using the specific antacid for reducing stomach acid just as the rejection in paragraph 23 of this action. Because the same compound is administered in the claims as in the prior art, the effect of the compound is expected to be the same since same compounds must have the same properties.

30. Therefore, a connection between stomach acidity and stereotypy is not required when the same compound is administered orally to animals such as horse.

31. Claims 34, 13-17, 20-23 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) in view of Brever et al. (US 3,946,115).

32. Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and “timothy hay” (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse’s inability to express foraging behavior (lines 1 and 2 of the abstract).

33. In Winskill’s study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat). Horse belongs to the taxonomic family of horses known as equidae so that claim 28 is met. Claims 29 and 30 are also met because Winskill teaches cribbing of horses as stereotypic behavior in horses.

9. Claim 34 is directed to a method of treating or ameliorating stereotypic behavior in an animal. The method of claim 34 comprises orally administering a composition comprising fat

and fiber to control pH of the stomach. Stomach antacid is optional. Thus, treatment or amelioration of stereotypy or minimization of risk of an animal developing stereotypy is the effect of the composition that is administered orally to the animal.

10. Thus, the composition of Winskill that is administered to the horse animal would also inherently produce the effect of treatment or amelioration of stereotypy or minimization of risk of the horse developing stereotypy noting that Winskill mentions confined horses show stereotypic behaviors. Since the method of claim 34 administers composition comprising fiber and oil to produce the effect of treatment or amelioration of stereotypy or minimization of risk of an animal developing stereotypy, oral administration of the composition of Winskill comprising fiber and oil would intrinsically produce the effects expected from the composition.

34. Since the horses were purchased and placed in the study, the horses have to have been weaned although the art is silent on that, and the examiners position is that the horses in Winskill's study encompasses the scope of recently weaned or weaning as recited in claim 14 or being weaned as recited in claim 22 or following weaning as recited in claim 23 or weaned as recited in claim 15. Regarding claim 13, examiner takes the position that the stomach pH of the horse is controlled before or shortly after the horse develops stereotypic behavior (claim 13) or before the stereotypic behavior is permanent or "fixed" as recited in amended claim 34 since it is the administration of the composition in claim 34 that results in the control of the pH. For claim 17, the composition of Winskill that is orally administered intrinsically inhibits the secretion of the acid in the stomach. Therefore, taking the teaching of Winskill, claims 13-16 would be prima facie obvious since it is the reduction in the acidity that produces the various effects and the time of administration of the feed would be any of the periods recited in the claims 13-16.

Response to Arguments

35. Applicant's arguments filed 11/02/09 have been fully considered but they are not persuasive. Applicant's arguments with respect to Winskill and Pagan as the arguments apply to the current rejections will be addressed.

36. Winskill:

37. Applicant argues that Winskill does not study stereotypic behavior in horses and that Winskill concludes on page 34, lines 4, 5, 10 and 11 that further research is needed to study the effect of Foodball on horses. Applicant then concludes that claims 11 and 34 and the claims dependent thereon are patentable over Winskill.

38. But, Winskill specifically says that it is known that feeding practices are thought to be important in the causation of stereotypies (page 26, second full paragraph) so that there is a suggestion in Winskill that feeding practices may be causation factors in stereotypies. So that even if further research is necessary to study the effect of the Foodball, Winskill in line 5 suggests that Foodball could have a possible role for their treatment or prevention. Therefore, claims 34, 13-17, 20-23 and 28-30 are not patentable over Winskill in view of Brever (Brever is applied in view of the amendment to claim 34).

39. In the remarks filed 8/10/09, applicant argues that there is no teaching in Winskill to treat or prevent stereotypy and as such the claims dependent therefrom are allowable. The examiner agrees that Winskill does not use the term prevent or treat stereotypy. But claim 34, is directed to a method that treats or ameliorates animal stereotypy by controlling stomach pH by oral administration of a composition that comprises fat and fiber. Thus a composition comprising fiber and fat when orally administered to the animal would control the pH of the stomach and

inherently produce the effect of treating or ameliorating animal stereotypy deriving from the effect of the composition. Therefore, oral administration of a composition comprising fiber and oil by Winskill to the horse animal would inherently produce the effect of treating and ameliorating stereotypy in the horse animal.

40. Declaration by Dr. Harris 2006:

The declaration by Dr. Harris filed 10/11/2006 was fully addressed and reproduced for applicant's benefit in the last office action (7/22/2008) and is again reproduced herein below.

Declaration by Dr. Harris 2008, 08 April:

41. Applicant argues that declaration by Dr. Harris submitted 4/29/2008 has not been properly considered. The examiner disagrees and reproduces the previous response below:

42. *The declaration under 37 CFR 1.132 filed 4/30/08 is insufficient to overcome the rejection of claims 1, 2, 7-18, 20-25, 28-30 and 34 based upon the rejections under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) in view of Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998) as set forth in the last Office action because: i) Winskill discloses the composition of the claims 1 and 2 except that the composition does not contain sodium carbonate. The result of feeding horses with feed composition containing fiber, oil (fat) and protein is a reduction in stall-walking or stereotypy according to the rejection of record and found in the whole document of Winskill with emphasis on the abstract; pages 27, 28, 32,33. ii) while Johnson may not have literally stated relationship between gastric acidity and equine stereotypy, it is noted that Johnson notes that horses fed with Founderguard had a drop fecal pH*

(abstract; pages 140-142), and reduction in abnormal behaviors such as wood chewing, grasping and bed eating, cribbing, wind-sucking (see the whole document of Johnson, with emphasis of page 140, left column; page 142, right column; and page 143, left column); Johnson further notes that it is known in the art that administration of sodium carbonate lowers the incidence of stereotypy (page 139, right column), which is a suggestion that sodium bicarbonate when administered would lower the incidence of stereotypy. It is further noted that Johnson orally feeds the horses. iii) since Johnson suggests that sodium carbonate administration lowers stereotypy and since the horses in Johnson are fed orally and since Winkill orally feeds horses that lead to reduction in stall-walking (stereotypy), the artisan would have reasonable expectation of success that addition of sodium carbonate to the feed of Winkill would lower the incidence of stall-walking. iv) regarding Pagan, it is noted that the title of the clinical paper is "Gastric Ulcers in Horses: A Widespread but Manageable Disease (page 159) and page 160, the title of the second full paragraph states: "Gastric Acid is a Major Cause." Pagan was relied upon for teaching neutralizing gastric acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox and the above three classes of drugs inhibit gastric secretion (pages 160 and 161). v) while applicant is of the opinion that a link between hindgut acidity and stereotypy in the horse would not have led the skilled artisan to believe that there is also a link between stomach acidity and stereotypy, it is noted that applicant has not provided factual evidence that there is no link between stomach acidity and stereotypy. It is known in the art and presented in the rejections that feeding horses with diets of fat and fiber and protein lowers fecal pH and incidence of stereotypy; and administration of

sodium carbonate lowers the incidence of stereotypy. vi) the evidence provided by applicant on 10/11/06 would not have led the artisan away from including sodium carbonate in a feed for horses because there is a teaching that food containing protein and fiber and fat lowers fecal acidity and reduces stereotypy/stall-walking (Winskill) and another that teaches sodium carbonate lowers the incidence of stereotypy and hindgut acidity (Johnson). Further, the declaration by Dr. Harris (10/11/06) supports oral administration of sodium carbonate or the obvious addition of sodium carbonate to the feed of Winskill to reduce stall-walking/stereotypy.

43. *Thus in all, the declaration is an opinion declaration that has not provided factual evidence as to why sodium carbonate cannot be administered orally to the horse, as to why the administration of sodium carbonate with a feed containing fat and fiber would not lower stereotypy and as to why the administration of sodium carbonate would not lower stereotypy as suggested by Johnson, and as to why there is no link between stomach acidosis and stereotypy in the horse.*

44. Applicant refers to Johnson and Willard that are no longer used as art against the claims and the examiner is not able to address art and rejections that are not of record.

45. Applicant argues that Dr. Harris presented evidence on the record that oral use of sodium bicarbonate or sodium carbonate. The examiner has re-reviewed the declaration filed 4/30/09 (date as entered in the PTO record) and does not find the evidence applicant refers to. Specifically, the opinion states, page 2 and 3 of the declaration:

“6. Differences between the claimed invention and the cited references, and reasons why a combination of the cited references would not render the claimed invention obvious to the person having ordinary skill in the art, are given below.

i. Winskill et al. does not teach or suggest any association between animal stereotypy and acidity of the intestinal tract.

ii. Johnson et al. does not teach or suggest that gastric acidity is associated with equine stereotypy.

iii. Johnson et al. does not teach or suggest oral administration of sodium carbonate to horses.

iv. Pagan does not teach or suggest that formation of ulcers, or any other acidity of the intestinal tract, is associated with stereotypic behaviour.

v. Disclosure of a link between hindgut acidity and stereotypy in the horse would not have led the skilled person to believe that there is also necessarily a link between stomach acidity and stereotypy.

vi. The person of ordinary skill in the art, in view of the evidence provided in nay Declaration filed 10/11106, would not in my opinion have included carbonate in the feed of horses in order to treat stereotypy."

46. From the above, it is noted that when the declaration talks about sodium carbonate, it refers to Johnson and Johnson is not art in the present rejection. Also, while the examiner acknowledges the expertise of Dr. Harris, contrary to applicant's argument, this declaration does not present/contain factual evidence on the record. Further also, Lambert selects the antacid from the group consisting of aluminum phosphate, dihydroxy-aluminum-sodium-carbonate, dicalcium phosphate, calcium carbonate and mixtures thereof (column 2, lines 1-4, 48-52) and calcium carbonate is one of the antacid. Also, claim 1 generically recites antacid with no

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mention of any specific antacids such as the sodium bicarbonate or sodium carbonate applicant is arguing for or against. Further, the “animal” as recited in claim 1, 2, 11, 14-17, 20-24 and 34 is a broad term that covers humans and sodium bicarbonate or sodium carbonate are known to be administered orally to humans. Thus, contrary to applicant's statement, the examiner fully addressed the declaration and did not gloss over the declaration. The claims are not specifically directed to method of treating stereotypy by administering antacid to a horse in need thereof.

47. To further show that the examiner fully addressed applicant's arguments and declaration, the following paragraphs from the office action of 02/09/09 at paragraphs 39 and 40 are reproduced for applicant:

48. *Regarding oral administration of sodium bicarbonate:* The applicant is referred to paragraph 9 above of the action where it is described that Lambert discloses an antacid composition that comprises antacid, 4.0-8.0% oil, antioxidant, and 46.0-84.5% carrier (column 2, lines 1-34; column 2, lines 5-47 and claims 1-3). The antacid is selected from the group consisting of aluminum phosphate, dihydroxy-aluminum-sodium-carbonate, dicalcium phosphate, calcium carbonate and mixtures thereof (column 2, lines 1-4, 48-52). The carrier is selected from the group consisting of ground wheat, spray dried whey, steam rolled oats and mixtures thereof (column 2, lines 11-13; column 3, lines 16-18). The antacid such as calcium carbonate is a stomach antacid meeting the requirement of the claimed composition to have stomach antacid; the carrier such as ground wheat or rolled oats or mixtures thereof meets the limitation of fiber and the amount of 46-84.5% of carrier, and specifically the 60.45%, derived from 30-45% ground wheat and 20.0% rolled oats (column 2, lines 33 and 34) meet the limitation

of 15-70% fiber or points within the disclosed range of 46-84.5% intersects points within the claimed range of 15-70% fiber of claims 1, 2. The composition of Lambert is administered to horses to reduce gastric acid (column 1, lines 52-54). Therefore, it is known to administer antacid such as calcium carbonate to horses. The Lambert art was filed March 12, 1998 and claims priority to March 13, 1997. This appears to be the state of the art in March or 1997 before applicant's invention.

49. Regarding oral administration of sodium carbonate: *Lambert orally administers calcium carbonate (priority date of 1997). The declaration continues to be ineffective in placing the claims in condition for allowance. Please refer to the reasons provided 12/21/06, reproduced 7/22/08 and herein.*

50. Evidence of unexpected result, teaching away of the prior art and long felt need: *The declaration continues to be insufficient to place the claims in condition for allowance in view of the rejections made herein. Lambert teaches the use of antacid in horses. Pagan uses antacid in the horse to treat ulcer. Antacid is optional in claim 34. Claim 11 administers antacid to treat stereotypy and the consequence or effect of antacid is also inherent or intrinsic to the antacid administered orally. Pagan, Winskill and Lambert, by administering the composition claimed to be administered to elicit the effect of treating stereotypy, also inherently or intrinsically treats stereotypy. There is no teaching away of these references in view of the claims.*

51. Applicant also argues that it is not surprising that feed containing fat, fiber and Neigh-Lox and also containing sodium carbonate lowers stomach acidity and stereotypy in general

because this is within the scope of the invention and that the examiner has the burden of showing that this is within the prior art or was obvious in view of the prior art.

52. The examiner respectfully notes that the case for obviousness of the claims over the cited art has been exhaustively made and the office action makes the case.

53. While the prior art does not make a link between stereotypy and stomach acid, claim 1 and those dependent there on are composition/product claims; ii) the method involves oral administration of antacid to produce certain effects. The prior art orally administers antacid and it is reasonable to expect that because the compounds administered are the same, the same effect would be expected from the compound. Same compounds must have the same effects. The burden was on applicant to show that the composition of the prior art references cited cannot produce the effect of treating stereotypy or lower gastric acid or minimize the risk of the animal developing ulcer or stereotypy.

54. No claim is allowed.

55. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

56. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

57. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

58. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

59. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618